

Remarks/Arguments:

Claims 27, 31-33, 37, 38, 41, 48, 52, 53, 55, and 56 are pending.

Elections/Restrictions

The Examiner has withdrawn from further consideration claims 28-30, 34-36, 39, 40, 42-47, 49-51, 54, and 57.

Claim Rejections Under Section 112

Claim 38 stands rejected under 35 U.S.C. § 112, paragraph 2, as being indefinite.

Specifically, the Office Action at page 3 states the following:

The claim fails to further limit the structure of the device of claim 37. The language of the claims [sic.] is directed to a method step for placing the first member adjacent to the chamber of the heart.

Applicant respectfully traverses this Section 112, second paragraph rejection. It is Applicant's position that dependent claim 38 does in fact further define the invention of claim 37, which is a structure claim to a device for treating a diseased heart. Claim 38 further requires that the "limited segment" comprise "at least fifty percent of a longitudinal length of said chamber." This feature is a further requirement to the "limited segment of said line" as found in claim 37.

Also, the remarks at page 3 of the Office Action with respect to claim 37 misconstrue claim 38, since these remarks indicate that claim 37 is a "method" claim. In fact, claim 37 defines the structure of a device. Thus, it appears that the Office Action misunderstands both claims 37 and 38.

Based on the above remarks, Applicant requests that the Section 112, second paragraph, rejection directed to claim 38 be withdrawn. It is Applicant's contentions that all pending claims are in full compliance with Section 112.

Claim Rejections Under Section 102

Claims 27, 31-33, 37, 38, 41, 48, 52, 53, 55, and 56 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Schweich, Jr., et al ("the Schweich Patent). Applicant respectfully traverses this Section 102(e) rejection.

The Schweich Patent issued on October 5, 1999, having a filing date of September 18, 1997. The Schweich Patent (according to the first page of the patent) is a continuation-in-part of Application Serial No. 08/778,277, filed January 2, 1997. But it is Applicant's contention that the Schweich Patent is not prior art to the subject application. The subject application is based on a Priority Application, Serial No: 08/581,914, filed January 2, 1996 (now U.S. Patent No. 5,957,977). Thus, the Priority Application precedes, by twelve months, the earliest possible filing date of the Schweich Patent. It is Applicant's contention that each of the pending claims finds support from the disclosure of the Priority Application (now U.S. Patent No. 5,957,977), and therefore as to each of these claims, the Schweich Patent is not prior art.

In support of its position that the Schweich Patent is not prior art because each of the pending claims is supported on the Priority Application (U.S. Patent No. 5,957,977), Applicant sets forth below, **in bold**, the specific portions of the Priority Application supporting each of the features of the pending claims.

Support in Priority Application (now U.S. Patent No. 5,957,977)

for the following pending claims:

27. A device [device 50; Fig. 2] for treating a heart [10; Figs. 1 and 4] by deforming one and only one chamber of the heart [left ventricle 12; col. 2, ln. 48; col. 3, Ins. 8-9, 20-28, 37-44; col. 4, Ins. 52-53; col. 5, Ins. 32-34, 46-54; col. 6, Ins. 58-62; col. 7, ln. 6; col. 8, Ins. 6-7, 35-37, and 65-66], said device comprising:

a first member configured to be positioned adjacent an exterior surface of said chamber and to selectively deform said chamber by applying pressure to said chamber [**generally col. 2, Ins. 40-41; col. 3, Ins. 49-51; specifically (i) external yoke 70 through gel-filled**

cushion portion 80 of yoke providing pressure over epicardial surface irregularities, col. 5, Ins. 36-44 and Figs. 4 and 6, and/or (ii) activator 74 with arm 75 and bands 84, col. 6, Ins. 58, 64-65; col. 7, Ins. 29-31, 42-44 and Figs. 5A, 5B, 7A, 7B], and

a second member coupled to said first member, wherein said second member is configured to restrict free movement of said chamber and to provide resistance against the pressure applied by said first member to said chamber [(i) internal stint 52 and cords 86; Figs. 3 and 6; col. 4, Ins. 59-61; col. 5, Ins. 55-58; col. 7, Ins. 53-54, and/or (ii) collar 70 through semi-rigid collar portion providing rigidity for gel-filled cushion portion 80, col. 3, Ins. 8-9; col. 5, Ins. 32-40; and Figs. 5A, 5B, and 6].

31. A method [col. 1, Ins. 7; col. 7, In. 59 to col. 8, In. 58] of treating a diseased heart [10; col. 1, Ins. 16-17] by deforming one and only one chamber of the heart [left ventricle 12; col. 2, In. 48; col. 3, Ins. 8-9, 20-28, 37-44; col. 4, Ins. 52-53; col. 5, Ins. 32-34, 46-54; col. 6, Ins. 58-62; col. 7, In. 6; col. 8, Ins. 6-7, 35-37, 65-66], said chamber having an outer wall [col. 4, In. 31], said method comprising the steps of:

providing a device [device 50; Fig. 2] having a first member configured to overlie a first portion of said outer wall of said chamber [generally col. 2, Ins. 40-41; col. 3, Ins. 49-51; specifically (i) external yoke 70 through gel-filled cushion portion 80 of yoke providing pressure, col. 5, Ins. 36-44; Fig. 6, and/or (ii) activator 74 with arm 75 and bands 84, col. 6, Ins. 58, 64-65; col. 7, Ins. 29-31, 42-44 and Figs. 5A, 5B, 7A, and 7B] and a second member attached to said first member, said second member configured to engage a second portion of said outer wall of said chamber [(i) internal stint 52 and cords 86; Figs. 3 and 6; col. 4, Ins. 59-61; col. 5, Ins. 55-58; col. 7, Ins. 53-54, and/or (ii) collar 70 through semi-rigid collar portion providing rigidity for gel-filled cushion portion 80, col. 3, Ins. 8-9; col. 5, Ins. 32-40; and Figs. 5A, 5B, and 6], and

causing said first member to press inwardly on said outer wall to form an indentation in said outer wall [generally col. 2, Ins. 40-41; col. 3, Ins. 49-51; specifically (i) external yoke 70 through gel-filled cushion portion 80 of yoke providing pressure, col. 5, Ins. 36-44; Fig. 6 and/or (ii) activator 74 with arm 75 and bands 84, col. 6, Ins. 58,

64-65; col. 7, Ins. 29-31, 42-44 and Figs. 5A, 5B, 7A, and 7B], while said second member restricts free movement of said chamber and resists the pressure applied by said first member to said chamber [(i) **internal stint 52 and cords 86; Figs. 3 and 6; col. 4, Ins. 59-61; col. 5, Ins. 55-58; col. 7, Ins. 53-54, and/or (ii) collar 70 through semi-rigid collar portion providing rigidity for gel-filled cushion portion 80, col. 3, Ins. 8-9; col. 5, Ins. 32-40; and Figs. 5A, 5B, and 6**].

32. The method of claim 31, wherein a plurality of first members are attached to said second member and each of said plurality of first members is configured to press inwardly on different selected portions of an outer wall of one chamber of said heart, each forming indentations in said wall and reducing the volume of said chamber [**external yoke 70 includes a plurality of bands 84 sized and configured for placement adjacent the exterior surface of the natural heart 10; Figs. 5A and 5B; col. 6, Ins. 18-29; col. 6, Ins. 53-62; col. 7, Ins. 29-33, and 43-49; col. 8, Ins. 4-6, and 65-67**].

33. The method of claim 32, wherein said plurality of said first members include portions configured to press inwardly on opposing portions of said outer wall of one chamber of said heart, each forming indentations in said wall and reducing the volume of said chamber [**external yoke 70 includes a plurality of bands 84 sized and configured for placement adjacent the exterior surface of the natural heart 10; Figs. 5A and 5B; col. 6, Ins. 18-29; col. 6, Ins. 53-62; col. 7, Ins. 29-33, and 43-49; col. 8, Ins. 4-6, and 65-67**].

37. A device [**device 50; Figs. 2, 4, 5A, and 5B**] for treating a diseased heart [**10; Figs. 1 and 4**] by deforming one and only one chamber of the heart [**left ventricle 12; col. 2, Ins. 48-51; col. 3, Ins. 8-9, 20-28, 37-44; col. 4, Ins. 52-53; col. 5, Ins. 32-34, 46-54; col. 6, Ins. 58-62; col. 7, ln. 6; col. 8, Ins. 6-7, 65-67**], said device comprising:

an elongated first member configured to be positioned adjacent said chamber along a line encircling a portion of an exterior surface of said chamber and to selectively deform said chamber by applying inward pressure to said chamber along a limited segment of said line [**generally col. 2, Ins. 40-41, and Ins. 49-51; col. 3, Ins. 7-9, 21-28, and 49-51; specifically (i) external yoke 70 through gel-filled cushion portion 80 of yoke**

providing pressure over epicardial surface irregularities, col. 5, Ins. 33-54; Figs. 4 and 6, and/or (ii) activator 74 with arm 75 and bands 84, col. 6, Ins. 18-29, 56-65; col. 7, Ins. 29-33, 42-59, and Figs. 5A, 5B, 7A, 7B], and

a second member coupled to said first member, wherein said second member is configured to be positioned adjacent a portion of an exterior surface of said chamber substantially opposite said first member to provide resistance against the pressure applied by said first member to said chamber [(i) internal stint 52 and cords 86; Figs. 3 and 6; col. 4, Ins. 59-60; col. 5, Ins. 55-58; col. 7, Ins. 53-55, and/or (ii) collar 70 through semi-rigid collar portion providing rigidity for gel-filled cushion portion 80, col. 3, Ins. 7-8; col. 5, Ins. 32-54; and Figs. 5A, 5B, and 6].

38. The device according to claim 37, wherein said limited segment comprises at least fifty percent of a longitudinal length of said chamber [col. 6, Ins. 56-62; and col. 8, Ins. 65-66].

41. A device [**device 50; Fig. 2**] for use in treating a natural heart [**10; col. 1, Ins. 16-17**] comprising:

at least two opposing members configured to be positioned adjacent portions of an external wall of a chamber of said natural heart and adapted to apply an indentation against at least one point on said external wall [**as to at least one opposing member, generally col. 2, Ins. 40-41; col. 3, Ins. 49-51; specifically (i) external yoke 70 through gel-filled cushion portion 80 of yoke providing pressure over epicardial surface irregularities, col. 5, Ins. 36-44, and Figs. 4 and 6, and/or (ii) activator 74 with arm 75 and bands 84, col. 6, Ins. 58, 64-65; col. 7, Ins. 29-36, 42-44, and Figs. 5A, 5B, 7A, 7B; AND as to at least another opposing member, (i) internal stint 52 and cords 86; Figs. 3 and 6; col. 4, Ins. 59-61; col. 5, Ins. 55-58; col. 7, Ins. 53-54, and/or (ii) collar 70 through semi-rigid collar portion providing rigidity for gel-filled cushion portion 80, col. 3, Ins. 8-9; col. 5, Ins. 32-40; and Figs. 5A, 5B, and 6]; and**

a connecting structure adapted to connect and restrain said members in a position indenting at least one point on said external wall [**bands 84; Figs. 5A and 5B; col. 6, Ins. 18-22, and 54-62; and col. 7, Ins. 43-55**].

48. A device [**device 50; Fig. 2**] for treating a natural heart [**10; col. 1, Ins. 16-17**], comprising:

at least two opposing members disposed adjacent portions of an exterior surface of a chamber of said heart, said portions generally disposed along segments of a single curve encircling said chamber [**as to at least one opposing member, generally col. 2, Ins. 40-41; col. 3, Ins. 49-51; specifically (i) external yoke 70 through gel-filled cushion portion 80 of yoke providing pressure over epicardial surface irregularities, col. 5, Ins. 36-44, and Figs. 4 and 6, and/or (ii) activator 74 with arm 75 and bands 84, col. 6, Ins. 58, 64-65; col. 7, Ins. 29-36, 42-44, and Figs. 5A, 5B, 7A, 7B; AND as to at least another opposing member, (i) internal stint 52 and cords 86; Figs. 3 and 6; col. 4, Ins. 59-61; col. 5, Ins. 55-58; col. 7, Ins. 53-54, and/or (ii) collar 70 through semi-rigid collar portion providing rigidity for gel-filled cushion portion 80, col. 3, Ins. 8-9; col. 5, Ins. 32-40; and Figs. 5A, 5B, and 6**]; and

a connecting structure connecting and restraining said members to selectively indent said portions [**bands 84; Figs. 5A and 5B; col. 6, Ins. 18-22, and 54-62; and col. 7, Ins. 43-55**].

52. A device [**device 50; Fig. 2**] for changing the shape of a natural heart [**10; col. 1, Ins. 6-17; col. 2, ln. 48; col. 3, Ins. 8-9, 20-28, 37-44; col. 4, Ins. 52-53; col. 5, Ins. 32-34, 46-54; col. 6, Ins. 58-62; col. 7, ln. 6; col. 8, Ins. 6-7, 35-37, 65-66**], comprising:

at least one first element configured to be disposed adjacent an outer surface of a chamber of the natural heart, and to apply pressure to a selected portion of the wall of said chamber [**generally col. 2, Ins. 40-41; col. 3, Ins. 20-28, 49-51; specifically (i) external yoke 70 through gel-filled cushion portion 80 of yoke providing pressure over**

epicardial surface irregularities, col. 5, Ins. 32-54, and Figs. 4 and 6, and/or (ii) activator 74 with arm 75 and bands 84, col. 6, Ins. 58, 64-65; col. 7, Ins. 29-33, 42-44; Figs. 5A, 5B, 7A, and 7B]; and

at least one second element connected to said first element and configured to hold said device in contact with said chamber wall [(i) internal stint 52 and cords 86; Figs. 3 and 6; col. 4, Ins. 59-61; col. 5, Ins. 55-58; col. 7, Ins. 53-54, and/or (ii) collar 70 through semi-rigid collar portion providing rigidity for gel-filled cushion portion 80, col. 3, Ins. 8-9; col. 5, Ins. 32-40; col. 6, Ins. 18-23; and Figs. 5A, 5B, and 6].

55. A device [device 50; Fig. 2] for treating a natural heart [10; col. 1, Ins. 6-17], comprising:

a first member configured to be positioned immediately adjacent a portion of an epicardial surface of the natural heart to restrict free motion of the heart [generally col. 2, Ins. 40-41; col. 3, Ins. 49-51; specifically (i) external yoke 70 through gel-filled cushion portion 80 of yoke providing pressure over epicardial surface irregularities, col. 5, Ins. 33-46; Figs. 4 and 6, and/or (ii) activator 74 with arm 75 and bands 84, col. 6, Ins. 58, 64-65; col. 7, Ins. 29-31, 42-44; and Figs. 5A, 5B, 7A, 7B]; and

a second member configured to apply a force to indent the external wall of the heart [(i) internal stint 52 and cords 86; Figs. 3 and 6; col. 4, Ins. 59-61; col. 5, Ins. 55-58; col. 7, Ins. 53-54, and/or (ii) collar 70 through semi-rigid collar portion providing rigidity for gel-filled cushion portion 80, col. 3, Ins. 8-9; col. 5, Ins. 32-46; and Figs. 5A, 5B, and 6].

56. The device of claim 55, wherein at least one of said first and second members comprise a surface adapted to provide equalized pressure over irregularities in an epicardial surface [col. 3, Ins. 7-9; and col. 5, Ins. 40-44].

Based on the foregoing comparison of the pending claims to the Priority Application, Applicant contends that the Schweich Patent is not prior art as to at least pending claims 27,

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31-33, 37, 38, 41, 48, 52, 53, 55, and 56. Applicant therefore requests that the Section 102(e) based on the Schweich Patent be withdrawn.

In view of the foregoing remarks and amendments, Applicants respectfully submit that claims 27, 31-33, 37, 38, 41, 48, 52, 53, 55, and 56 are in condition for allowance. Reconsideration and allowance of all pending claims are respectfully requested.

Respectfully submitted,

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